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09/862,417	05/23/2001	Xiao Bing Wang	55861-00007	8468

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/862,417	Applicant(s) Wang
	Examiner Arun Chakrabarti	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Specification

1. Claim 38 is objected to under 37 CAR 1.75© as being in improper form because a multiple dependent claim 38 cannot depend on another multiple dependent claim 28. See MPEP § 608.01(n). Accordingly, the claim 38 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

2.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 27 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 27, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 33 is rejected over the recitation of the phrase, “can be”. Regarding claim 33, the phrase "can be" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-4, 7, 9-16, 18-37, and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Monforte et al. (U.S. Patent 5,965,363) (October 12, 1999).

Monforte et al teach a method for detecting or quantifying a target nucleic acid in a sample (Abstract) comprising:

a) preparing a primer or primers specifically matched to a predetermined position of the target nucleic acid (Example 3, Column 24, lines 36-41);

b) annealing the primer or primers from a) with the target nucleic acid under high stringency conditions to obtain a primer-nucleic acid duplex at the predetermined position of the target nucleic acid (Example 3 and Figures 3-12);

c) mixing the primer-nucleic acid duplex from b) with a mixture comprising:

(1) one or two or three types of free non-terminator nucleotides and at least one type of non-terminator nucleotide that is optionally labeled with a detectable marker (Column 22, line 65 to Column 23, line 12 and Example 4), and

(2) with or without a type of terminator nucleotide that is different from the one or two or three types of non-terminator nucleotides in (1) (Column 22, line 65 to Column 23, line 12 and Example 4);

d) performing the primer extension by enzymatic or chemical reaction in an appropriate buffer; and

e) detecting or quantifying the amount of labeling signal in the primer extended nucleotides, or

f) detecting or quantifying the amount of extended primers by mass spectrometry (Abstract, Examples 3, and 5-7 and Figures 3-12).

Monforte et al teach a method, wherein the primer is an oligodeoxyribonucleic acid primer (Examples 3, and 5-7 and Figures 3-12).

Monforte et al teach a method, wherein the nucleic acid of interest is a deoxyribonucleic acid (Examples 3, and 5-7 and Figures 3-12).

Monforte et al teach a method, wherein the non-terminator nucleotide is deoxyribonucleotide (Column 22, line 65 to Column 23, line 12 and Example 4).

Monforte et al teach a method, wherein at least one non-terminator nucleotide is labeled with a detectable marker (Figures 3-12 and Example 3).

Monforte et al teach a method, wherein the detectable marker comprises an enzyme or protein moiety, radioactive isotope, a fluorescent moiety or a chemical group (Figures 3-12 and Example 3).

Monforte et al teach a method, wherein the non-terminator and terminator nucleotides are unlabeled and detecting or quantifying step is carried out by analyzing amount of extended primers using mass spectrometry (Examples 3, and 5-7 and Figures 3-12).

Monforte et al teach a method, wherein the enzyme is template dependent thermophilic DNA polymerase (Example 1).

Monforte et al teach a method, wherein the target nucleic acid is synthesized enzymatically in vitro by polymerase chain reaction ().

Monforte et al teach a method, wherein the target nucleic acid comprises non-natural nucleotide analogs (Column 22, line 65 to Column 23, line 20).

Monforte et al teach a method, wherein the target nucleic acid comprises genomic DNA from an organism (Example 5).

Monforte et al teach a method, wherein the organism is a plant, microorganism, bacteria, virus (Example 1 teaches that target nucleic acid can be any sequence, Column 24, lines 3-7).

Monforte et al teach a method, wherein the organism is a vertebrate or invertebrate (Example 5).

Monforte et al teach a method, wherein the organism is a mammal (Example 5).

Monforte et al teach a method, wherein the organism is a human being (Example 5).

Monforte et al teach a method, wherein an amplification step is performed on the target nucleic acid (Examples 3, 5-7).

Monforte et al teach a method, wherein the amplification step comprises polymerase chain reaction (Examples 3, 5-7).

Monforte et al teach a method, wherein the primer comprises one or more moieties that permit affinity separation of the primer from the unincorporated reagent and/or the nucleic acid of interest (Figures 3-12 and Examples 3, 5-7).

Monforte et al teach a method, wherein the primer comprises one or more moieties that allows immobilization of primer onto a solid support to produce an immobilized primer sequence (Examples 3 and 5).

Monforte et al teach a method, wherein the moieties comprises a special chemical group such as biotin (Examples 3 and 5 and Figures 3-12).

Monforte et al teach a method, wherein the moieties comprises a DNA sequence that allows the primer to link to a solid support via base pairing to a complementary sequence present in solid support (Example 5).

Monforte et al teach a method, wherein the primer is directly synthesized on a solid support to produce an immobilized primer sequence (Examples 3 and 5).

Monforte et al teach a method, wherein the synthesis is accomplished by enzymatic or chemical or physical method (Examples 3 and 5).

Monforte et al teach a method, wherein the primer is reversibly immobilized onto a solid support to produce an immobilized target nucleic acid sequence (Figures 7-8).

Monforte et al teach a method, wherein the primer can be cleaved from the solid support by a chemical, enzymatic or physical process (Figures 6-8, and 12 and Examples 3 and 5).

Monforte et al teach a method, wherein the target nucleic acid is reversibly immobilized via a photocleavable bond onto a solid support to produce an immobilized target nucleic acid sequence (Figures 7-8).

Monforte et al teach a method, wherein the target nucleic acid can be cleaved from the solid support by a chemical, enzymatic or physical process (Figures 5-12 and Examples 5-6)

Monforte et al teach a method, wherein the immobilization is accomplished by hybridization between a complementary capture nucleic acid molecule, which has been previously immobilized to a solid support and a portion of the nucleic acid molecule, which is distinct from the target nucleic acid sequence (Figures 7-8, 10 and Examples 5-6).

Monforte et al teach a method, wherein the immobilization is accomplished via direct bonding between the solid support and a portion of the nucleic acid molecule, which is distinct from the target nucleic acid sequence (Figure 10).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 5, 6, 8, and 17 are rejected under 35 U.S.C. 103(a) over Monforte et al. (U.S. Patent 5,965,363) (October 12, 1999) in view of Mizusawa et al. (Nucleic Acids Research, (1986), Vol. 14(3), pages 1319-1324).

Monforte et al teach the method of claims 1-4, 7-16, 18-37, and 39-40 as described above.

Monforte et al do not teach the method, wherein the terminator is dideoxyribonucleotide.

Mizusawa et al. teach the method, wherein the terminator is dideoxyribonucleotide (Abstract and MATERIALS AND METHODS Section and Figure 1).

Monforte et al do not teach the method, wherein a combination of non-terminator and terminator nucleotide mix is: dCTP, dGTP, dTTP, and ddATP.

Mizusawa et al. teach the method, wherein a combination of non-terminator and terminator nucleotide mix is: dCTP, dGTP, dTTP, and ddATP (MATERIALS AND METHODS Section, Page 1320, last sentence).

Monforte et al do not teach a method, wherein the terminator nucleotide is labeled with or without a detectable marker that is different from the marker labeled with non-terminator nucleotides.

Mizusawa et al. teach a method, wherein the terminator nucleotide is labeled with or without a detectable marker that is different from the marker labeled with non-terminator nucleotides (Figures 1-2).

Monforte et al do not teach the method, wherein the non-natural nucleotide analogs comprise 7-deaza-2'-deoxyguanosine.

Mizusawa et al. teach the method, wherein the non-natural nucleotide analogs comprise 7-deaza-2'-deoxyguanosine (Abstract and MATERIALS AND METHODS Section and Figures 1-2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method, wherein the non-natural nucleotide analogs comprise 7-deaza-2'-deoxyguanosine of Mizusawa et al. in the method of Monforte et al., since Mizusawa et al. states, "Thus we conclude that the dideoxy chain termination procedure is improved by use of dC7GTP instead of dGTP because compression of bands is greatly reduced (Page 1323, last sentence) ". An ordinary practitioner would have been motivated to substitute and combine the method, wherein the non-natural nucleotide analogs comprise 7-deaza-2'-deoxyguanosine of Mizusawa et al. in the method of Monforte et al., in order to achieve the express advantages , as noted by Mizusawa et al., of a revised methodology, which provides the improvement of the dideoxy chain termination procedure by use of dC7GTP instead of dGTP because compression of bands is greatly reduced.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703)

306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

August 5, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600